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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/813,483	03/29/2004	Jun Liu	P2026R1	5594
9157	7590	03/17/2005	EXAMINER	
GENENTECH, INC. 1 DNA WAY SOUTH SAN FRANCISCO, CA 94080			KIM, YUNSOO	
			ART UNIT	PAPER NUMBER
			1644	

DATE MAILED: 03/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/813,483

Applicant(s)

LIU ET AL.

Examiner

Yunsoo Kim

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 18, 19 and 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17, 20 and 22-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>5/28/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's amendment, filed in 1/5/05 is acknowledged.

Claims 1, and 10-19 are amended.

Claims 28-50 are withdrawn.

Claims 1-27 are pending.

2. Applicant's election without traverse of Group II, drawn to a stable liquid formulation comprising an antibody with an elected species of rhuMAbE25 in the reply filed on 1/5/05 is acknowledged.

Accordingly, claims 18, 19 and 21 are withdrawn from further consideration by examiner 37 CFR.1.142(b) as being drawn to a nonelected species.

Claims 1-17, 20, 22-27 read on antibody with the species rhuMAbE25 are under consideration in the instant application.

3. Sequence compliance: The instant application appears to be in sequence compliance for patent applications containing nucleotide sequence and/or amino acid sequence disclosures.

4. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged.

5. Applicant's IDS, filed on 5/28/04 is acknowledged.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1-17, 20, 22-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Andya et al. (WO 97/04801, IDS ref. No.18) in view of Relton et al. (WO 97/45140), Kaisheva et al. (US2003/0113316) and Merck Index (Merck Index, 10th Ed, 1983, p.797-798).

Andya et al. teach antibody formulations comprising rhuMAbE25 (p.3, lines 29-36, Figs. 9-19) in 3-15mM Histidine (p.15, lines 2-6) at pH 5-7 (p.15, lines 2-3) and 0.005-0.05% polysorbate (p.15, lines 24-34).

Andya et al. further teach the antibody formulations having an osmotic pressure of 250-350 mOsm (p. 9, lines 6-9, Fig. 13), a concentration of antibody ranges from at least 80mg/ml to 300mg/ml which includes 90-150mg/ml (p. 3, lines 8-10), reconstituted formulation being 2-40 times greater than the concentration prior to the lyophilization (p.1, lines 32-35), container enclosing the formulation (p.18, lines 16-30), and various administration methods including injection devices, syringe and auto-injector (i.e. needless devices p.17, lines 30-35).

Andya et al. also teach a concentration of lyoprotectant range at 30mM to about 300mM by using trehalose (p. 15, lines 8-15).

The claimed invention differs from the reference teachings only by the recitation arginine-HCl and having kinematic viscosity less than 50 cs (cs equals to cP as acknowledged in the specification p.22 of the instant application) and using arginine-HCl in antibody formulation.

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However, Relton et al. teach the kinematic viscosity ranges 1-9 cP (p.9, Table 1 (b)) and Kaisheva et al. teach addition of cyroprotectant (additional excipient, i.e. trehalose and arginine) to provide stability to the protein against freezing-induced stress.

As evidenced by the Merck Index, arginine is strong alkaline and to maintain the pH 5.5 –7 of the formulation of Andya et al. addition of acid or association with HCl would be required. Thus, the teachings of Kaisheva et al. meet the limitations of the invention.

It would have been obvious to one of the ordinary skill in the art at the time the invention was made to employ kinematic viscosity taught by Relton et al. as a measure of protein viscosity and addition of arginine taught by Kaisheva in the immunoglobulin preparation taught by Andya et al. as in claimed invention.

One of the ordinary skill in the art at the time the invention was made would have been motivated to do so because the teaching of Kaisheva et al. and Relton et al. by adding arginine as a form of cryoprotectant and kinematic viscosity to monitor viscosity of the formulation is an obvious way to improve stability of antibody formulation and ensure the viscosity quality of claimed invention. Thus, it is expected to combine teachings above to improve the stability of antibody preparation as in the claimed invention.

From the combined teachings of references, one of ordinary skill in art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of the ordinary skill in the art at the time the invention was made, as evidenced by references, especially in the absence of evidence to the contrary.

No claims are allowable.

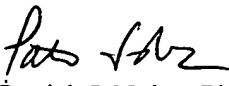
9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yunsoo Kim whose telephone number is 571-272-3176. The examiner can normally be reached on Monday thru Friday 8:30 - 5:00PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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March 1, 2005


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